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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,422	01/16/2004	Leif Andersson	62781.000013	5639

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EXAMINER

WOOLWINE, SAMUEL C

ART UNIT

PAPER NUMBER

1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/758,422	ANDERSSON ET AL.	
	Examiner	Art Unit	
	Samuel Woolwine	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 1 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status

Applicant's amendment filed 11/27/2006 is acknowledged. Currently, claims 1 and 10 are pending in the application. In the previous Office action dated 6/27/2006, the examiner indicated that claim 35 would be allowable if properly amended to overcome the rejection under 35 U.S.C. 112, 2nd paragraph and presented in independent form. However, the manner in which Applicant's have amended claims 1 and 10 to incorporate the limitations of claim 35 has raised a new issue and grounds for rejection under 35 U.S.C. 112, 1st paragraph, as discussed below.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/450,651, filed on February 4, 2000. The examiner apologizes for this oversight and appreciates Applicant's provision of copies of these documents notwithstanding.

Specification

The disclosure is objected to because of the following informalities: the substitute specification filed 11/12/2004, page 38, seems to have a minor typographical error. Under the heading BspHI digest, BstUI is indicated as the enzyme: "5 units *BstUI*". It is apparent from the context that this should read "5 units *BspHI*".

In addition, pages 73 and 74 of the substitute specification filed 11/12/2004 make reference to figure 15 (first and third paragraph under "Results"). This is also noted in the originally filed specification, page 71. It appears this reference to figure 15 should

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actually reference figure 12, as figure 12 contains the elements described in this part of the specification, and since there is no figure 15 in the application.

Appropriate correction is required.

Claim Objections

Claims 1 and 10 are objected to because of the following informalities: the amended claims recite "BspFHI", whereas the original claims and disclosure recite "BspHI". Appropriate correction is required.

Drawings

The drawings are objected to because the numbering of the nucleotide positions is in error, which results in discrepancies between the actual positions where polymorphisms occur in figure 1 and the positions in the pending claims. There are, with the exception of the second line of the sequence, 51 residues per line. Thus position 75, plus 51, yields position 126, plus 51, yields position 177, etc. However, position 279, plus 51, does not yield position 329 as indicated in figure 1, but rather yields a position number of 330. This error throws off the numbering for the rest of the figure. In addition, as currently shown in figure 1, a G to A substitution occurs at position 369 (counting backward from the "380" or forward from the "329" as indicated in figure 1), whereas the claims indicate a polymorphism at position 370. Therefore the position numbers of the polymorphisms in figure 1 at least in some cases do not agree with the position numbers of the polymorphisms recited in the claims. The examiner has not further assessed figure 1 for other possible numbering errors, and Applicant is

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advised to thoroughly review figure 1 for correctness prior to submitting substitute drawings.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Response to Arguments The rejections of all claims other than claims 1 and 10 made in the previous Office action are hereby withdrawn in view of the claim cancellations.

The rejection of claim 1 under 35 U.S.C. 102(b) and the rejection of claim 10 under 35 U.S.C. 103(a) are withdrawn in view of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the embodiment of claim 1 wherein said breed determinant gene is α MSHR, does not reasonably provide enablement for the embodiment of claim 1 wherein said breed determinant gene is KIT. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim 1 requires that the animal is a pig, and that the analysis step (ii) comprises restriction fragment length polymorphism (RFLP) analysis, involving digesting the pig nucleic with one or more of the restriction enzymes BstUI, HhaI and/or BspHI. Alternatively, analysis step (ii) involves identification of a polymorphism at nucleotide position 283, 305, 363, 370, 491, 727, 729, 1162, or between positions 60 and 70, or between positions 1005 and 1010 of the sequence of the pig α MSHR gene. Neither of these analysis alternatives is enabled with respect to the KIT gene.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to analysis of the genotype of a pig (or pig product), and making determinations as to the breed origin of the pig (or pig product) based on the genotype. The invention is the class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims are drawn to analysis of either the KIT gene or the α MSHR gene of a pig.

Quantity of Experimentation

To the extent the examiner is able to determine, the quantity of experimentation is not an issue here.

The unpredictability of the art and the state of the prior art

To the extent the examiner is able to determine, the unpredictability of the art and the state of the prior art is not an issue here.

Working Examples

The specification provides working examples showing polymorphisms in the pig α MSHR gene detectable by RFLP using the restriction enzymes BstUI, HhaI and/or BspHI. The specification provides no working examples showing polymorphisms in the pig KIT gene detectable by RFLP using the restriction enzymes BstUI, HhaI and/or BspHI. The specification provides working examples showing polymorphisms in the pig α MSHR gene at positions 283, 305, 363, 370, 491, 727, 729, 1162, or between

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positions 60 and 70, or between positions 1005 and 1010. The specification provides no working examples showing polymorphisms in the pig KIT gene at positions 283, 305, 363, 370, 491, 727, 729, 1162, or between positions 60 and 70, or between positions 1005 and 1010.

Guidance in the Specification.

There is no guidance provided in the specification as to how an analysis step comprising restriction fragment length polymorphism (RFLP) analysis, involving digesting the pig nucleic with one or more of the restriction enzymes BstUI, HhaI and/or BspHI, could be used to analyze alleles of the pig KIT gene in order to achieve any of (a) differentiating animals and animal products on the basis of breed origin, (b) determining or testing the breed origin of an animal product, or (c) validating an animal product. Nor is there guidance in the specification as to how identifying polymorphisms at specific positions in the pig α MSHR gene serves to analyze alleles of the pig KIT gene to achieve (a), (b) or (c) as stated above.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

Based on the breadth of the claim, i.e. inclusion of analysis of the KIT gene, and the requirement of the claim that the analysis steps include analyses that are clearly directed to the α MSHR gene, the specification simply fails to provide enablement for the claim in its current form. This rejection could be overcome by limiting claim 1 to the pig α MSHR gene.

Allowable Subject Matter

Claims 1 and 10 are free of the prior art.

The following is a statement of reasons for the indication of allowable subject matter: To the extent that the claims are limited to the pig α MSHR gene, claims 1 and 10 are allowable over the prior art. The claims require either one or both of the following analysis steps in order to analyze the allele(s) of the pig α MSHR gene:

(i) RFLP analysis involving digestion of pig nucleic acid with one or more of BstUI, HhaI and BspHI

(ii) identification of a polymorphism at nucleotide position 283, 305, 363, 370, 491, 727, 729, 1162, or between positions 60 and 70, or between positions 1005 and 1010 of the pig α MSHR gene

With regard to analysis (ii), there is no prior art disclosing polymorphisms at these positions of the pig α MSHR gene. With regard to analysis (i), there is no prior art disclosing analysis of an allele of the pig α MSHR gene by RFLP analysis using BstUI, HhaI and/or BspHI. The closest prior art is Mariani et al (Journal of Heredity (1996) vol 87, pp 272-276), which discloses analysis of alleles of the *TAT* and *S0016* loci, which are genetically linked to the *E* locus, which according to Mariani "most certainly" encodes the MSH-R gene product (see page 273, "RFLP Analysis" and see page 274, first paragraph "Discussion" and see figure 2). Mariani showed that different alleles of *TAT* and *S0016* could be identified using RFLP analysis involving digestion of pig DNA with TaqI (see page 273, "RFLP Analysis"). While one of ordinary skill in the art might have had a reasonable expectation that this RFLP analysis would correlate with a

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particular allele of the *E* locus (and thus the pig α MSHR gene), there would have been no motivation nor a reasonable expectation of success in modifying the method disclosed by Mariani to include digestion with BstUI, HhaI and/or BspHI, since the recognition site for TaqI is completely different than the recognition sites for these other enzymes. Only after isolating and sequencing the different alleles of the pig α MSHR gene itself, along with the particular sequence polymorphisms therein, as Applicants have done, does such motivation and expectation of success materialize.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

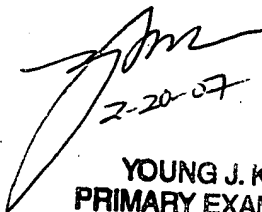
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SCW


2-20-07
YOUNG J. KIM
PRIMARY EXAMINER